JAP15 Rec'd PCT/PTO 13 JUN 2006

PTO-1390 (Rev. 02-2005)
Approved for use through 3/31/2007. OMB 0651-0021
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| TRANSMITTAL LETTER TO THE UNITED STATES | ATTORNEY'S DOCKET NUMBER LP-31005-US | | | | | | | | | |
|---|--|--|--|--|--|--|--|--|--|--|
| DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371 | U.S. APPLICATION NO. (If known, see 37 CFR 1.5) 10/569863 | | | | | | | | | |
| INTERNATIONAL APPLICATION NO. INTERNATIONAL FILING DATE | PRIORITY DATE CLAIMED | | | | | | | | | |
| PCT/DK2004/000574 30 August 2004 | 29 August 2003 | | | | | | | | | |
| TITLE OF INVENTION SOLID DISPERSIONS COMPRISING TACROLIMUS | | | | | | | | | | |
| APPLICANT(S) FOR DO/EO/US HOLM et al. | | | | | | | | | | |
| Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: | | | | | | | | | | |
| This is a FIRST submission of items concerning a submission under 35 U.S.C. 371. | | | | | | | | | | |
| This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. | | | | | | | | | | |
| This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. | | | | | | | | | | |
| The US has been elected (Article 31). | | | | | | | | | | |
| 5. A copy of the International Application as filed (35 U.S.C. 371(c)(2)) | A copy of the International Application as filed (35 U.S.C. 371(c)(2)) | | | | | | | | | |
| a. is attached hereto (required only if not communicated by the Internation | a. is attached hereto (required only if not communicated by the International Bureau). | | | | | | | | | |
| b. has been communicated by the International Bureau. | b. has been communicated by the International Bureau. | | | | | | | | | |
| c. is not required, as the application was filed in the United States Recei | c. is not required, as the application was filed in the United States Receiving Office (RO/US). | | | | | | | | | |
| 6. An English language translation of the International Application as filed (35 U.S | .C. 371(c)(2)). | | | | | | | | | |
| a is attached hereto. | | | | | | | | | | |
| b. has been previously submitted under 35 U.S.C. 154(d)(4). | b. has been previously submitted under 35 U.S.C. 154(d)(4). | | | | | | | | | |
| 7. Amendments to the claims of the International Application under PCT Article 19 | Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) | | | | | | | | | |
| a are attached hereto (required only if not communicated by the Intern | a are attached hereto (required only if not communicated by the International Bureau). | | | | | | | | | |
| b. have been communicated by the International Bureau. | b. have been communicated by the International Bureau. | | | | | | | | | |
| c. have not been made; however, the time limit for making such amend | c. have not been made; however, the time limit for making such amendments has NOT expired. | | | | | | | | | |
| d. have not been made and will not be made. | | | | | | | | | | |
| 8. An English language translation of the amendments to the claims under PCT A | Article 19 (35 U.S.C. 371(c)(3)). | | | | | | | | | |
| 9. An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). | • | | | | | | | | | |
| An English language translation of the annexes of the International Preliminary Article 36 (35 U.S.C. 371(c)(5)). | An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). | | | | | | | | | |
| Items 11 to 20 below concern document(s) or information included: | | | | | | | | | | |
| 11. An Information Disclosure Statement under 37 CFR 1.97 and 1.98. | | | | | | | | | | |
| 12. An assignment document for recording. A separate cover sheet in compliance | with 37 CFR 3.28 and 3.31 is included. | | | | | | | | | |
| 13. A preliminary amendment. | A preliminary amendment. | | | | | | | | | |
| An Application Data Sheet under 37 CFR 1.76. | An Application Data Sheet under 37 CFR 1.76. | | | | | | | | | |
| 15. A substitute specification. | A substitute specification. | | | | | | | | | |
| A power of attorney and/or change of address letter. | | | | | | | | | | |
| A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825. | | | | | | | | | | |
| 18. A second copy of the published International Application under 35 U.S.C. 154(c | A second copy of the published International Application under 35 U.S.C. 154(d)(4). | | | | | | | | | |
| 19. A second copy of the English language translation of the international application | A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4). | | | | | | | | | |
| 20. Other items or information: Unexecuted Declaration and Power of Attorney and | Other items or information: Unexecuted Declaration and Power of Attorney and International Search Report | | | | | | | | | |

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mall Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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| | | U.S. APPLICATION NO. (if known, see 37 CFR 1.5) INTERNATIONAL APPLICATION NO. 10/569863 PCT/DK2004/000574 | | | | | | ION NO. | ATTORNEY'S DOCKET NUMBER | | |
|------------|--|---|---------|-----------------|---|---------------------------|----------------------------|---------------------|---------------------------|---------------|--|
| | 10/5 | | | | | | | 74 | LP-31005-US | | |
| | | The following fees have been submitted | | | | | | CALCULATIONS | PTO USE ONLY | | |
| | 21. | Basic national fee\$300 | | | | | | | \$ | | |
| | 22. Examination fee If International preliminary examination report prepared by USPTO and all claims satisfy provisions of PCT Article 33(1)-(4) | | | | | | \$100 | \$ | | | |
| | 23. Search fee Search Tee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority | | | | | | | \$ | | | |
| | TOTAL OF 21, 22 and 23 = | | | | | | | \$ | | | |
| | Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof. | | | | | | | | | | |
| | Tota | l Sheets | Ext | ra Sheets | Number of each additional 50 or fraction thereof (round up to a whole number) | | RA | TE. | | | |
| | | - 100 = | | /50 = | | | x \$25 | 0 | \$ | | |
| | Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(h)). | | | | | | | | \$ 130 | | |
| | | CLAIMS | | NUMBI | ER FILED NUMBER EXTRA | | R | ATE | \$ | | |
| | T | otal claims | | | - 20 = | | x \$ | 50 | \$ | | |
| | <u>_</u> | endent cla | | | - 3 = | | x \$ | 200 | \$ 0 | | |
| | MULT | IPLE DEP | ENDE | NT CLAIM(S | S) (if applicable) | | | 360 | \$ | | |
| | | TOTAL OF ABOVE CALCULATIONS = | | | | | | | \$ | | |
| | [√]^ | pplicant cla | aims sr | mall entity sta | atus. See 37 CFR | 1.27. Fees above are redu | ced by 1/2. | | -\$65 | | |
| | <u> </u> | | | | | | | BTOTAL = | \$ 65 | | |
| | | Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)). | | | | | | | \$ | | |
| | TOTAL NATIONAL FEE = | | | | | | | \$ 65 | | | |
| | Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanious an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property | | | | | | | ompanied + | \$ | · | |
| | TOTAL FEES ENCLOSED = | | | | | | | | \$ 65 | | |
| 06/16/2008 | 006 GFREY1 00000133 10569863 | | | | | | | | Amount to be refunded: | \$ | |
| 01 FC:2617 | 65.00 OP | | | | | | | | Amount to be charged: | \$ | |
| | a | a. A check in the amount of \$ to cover the above fees is enclosed. b. Please charge my Deposit Account No in the amount of \$ to cover the above fees. A duplicate copy of this sheet is enclosed. | | | | | | | | | |
| | с. | | | | | | | | or credit any overpayment | to Deposit | |
| | d. Fees are to be charged to a credit card. WARNING: Information on this form may become public included on this form. Provide credit card information and authorization on PTO-2038. | | | | | | lic. Credit card informati | on should not | | | |
| | NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive and granted to restore the International Application to pending status. SEND ALL CORRESPONDENCE TO: Customer No. 25538 Cheryl | | | | | | | on to revive | (37 CFR 1.137(a) or (b)) | must be filed | |
| | | | | | | | | V. Agus | | | |
| | | | | | | | | GNATURE Cheryl I | U H. Agris | | |
| | Da | Date: JUNE 13, 2006 NAME 34,086 | | | | | | | | | |
| | REGISTRATI | | | | | | | | JN NUMBER | | |

Attorney Docket No.: LP-31005-US PATENT

IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

INTERNATIONAL APPLICATION NO. PCT/DK2004/000574

US APPLN. Ser. NO: 10/569863

INTERNATIONAL FILING DATE: 30 August 2004

PRIORITY DATE: 29 August 2003

TITLE: SOLID DISPERSIONS COMPRISING TACROLIMUS

APPLICANT(S) FOR RO/US: HOLM, Per and NORLING, Tomas **EXPRESS MAIL CERTIFICATE**

Mail Stop PCT Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Express Mail Label No. EV746361557US

Date of Deposit: June 13, 2006

I hereby certify that the following attached paper(s) or fee

- 1. Transmittal Letter to the DO/EO/US
- 2. PTO 2038 (Fee of \$65.00)
- 3. Declaration and Power of Attorney (executed)
- 4. International Search Report
- 5. Information Disclosure Statement
- 6. PTO 1449 Form
- 7. References (9-Foreign Patent Documents and other documents)

are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" under 37 C.F.R. 1.10 on the date indicated above and is addressed to Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Cheryl H. Agris
(Name of person mailing paper(s) or fee)

(Signature of person mailing paper(s) or fee)

Mailing address: P.O. Box 806, Pelham, N.Y. 10803; telephone: (914) 712-0093